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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 5

**Delegation of Authority and Organization; Center for Food Safety and Applied Nutrition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the general redelegation of authority from the Commissioner of Food and Drugs to other officers of FDA. The amendment delegates to the Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); the Director, Office of Regulations and Policy, CFSAN; and the Director, Office of Premarket Approval, CFSAN authority to implement the Federal Food, Drug, and Cosmetic Act (the act), as amended hereafter. This redelegation is necessary to improve the efficiency of program operations.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** Section 309 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 409 of the act (21 U.S.C. 348). New section 409(h) of the act requires manufacturers or suppliers of food-contact substances to notify the

Secretary of Health and Human Services (and by delegation, the Commissioner of Food and Drugs), at least 120 days prior to the introduction or delivery for introduction into interstate commerce, of the identification and use of food-contact substances, and to provide information showing that the substance is safe according to the standards of section 409(c)(3)(A) of the act.

FDA is amending the general redelegation of authority from the Commissioner of Food and Drugs to the Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); the Director, Office of Regulations and Policy, CFSAN; and the Director, Office of Premarket Approval, CFSAN authority to implement the act, as amended hereafter. This redelegation is necessary to improve the efficiency of program operations. Further redelegation of the authorities is not authorized at this time. Authority delegated to a position may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

### **List of Subjects in 21 CFR Part 5**

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

## **PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

1. The authority citation for 21 CFR part 5 continues to read as follows:

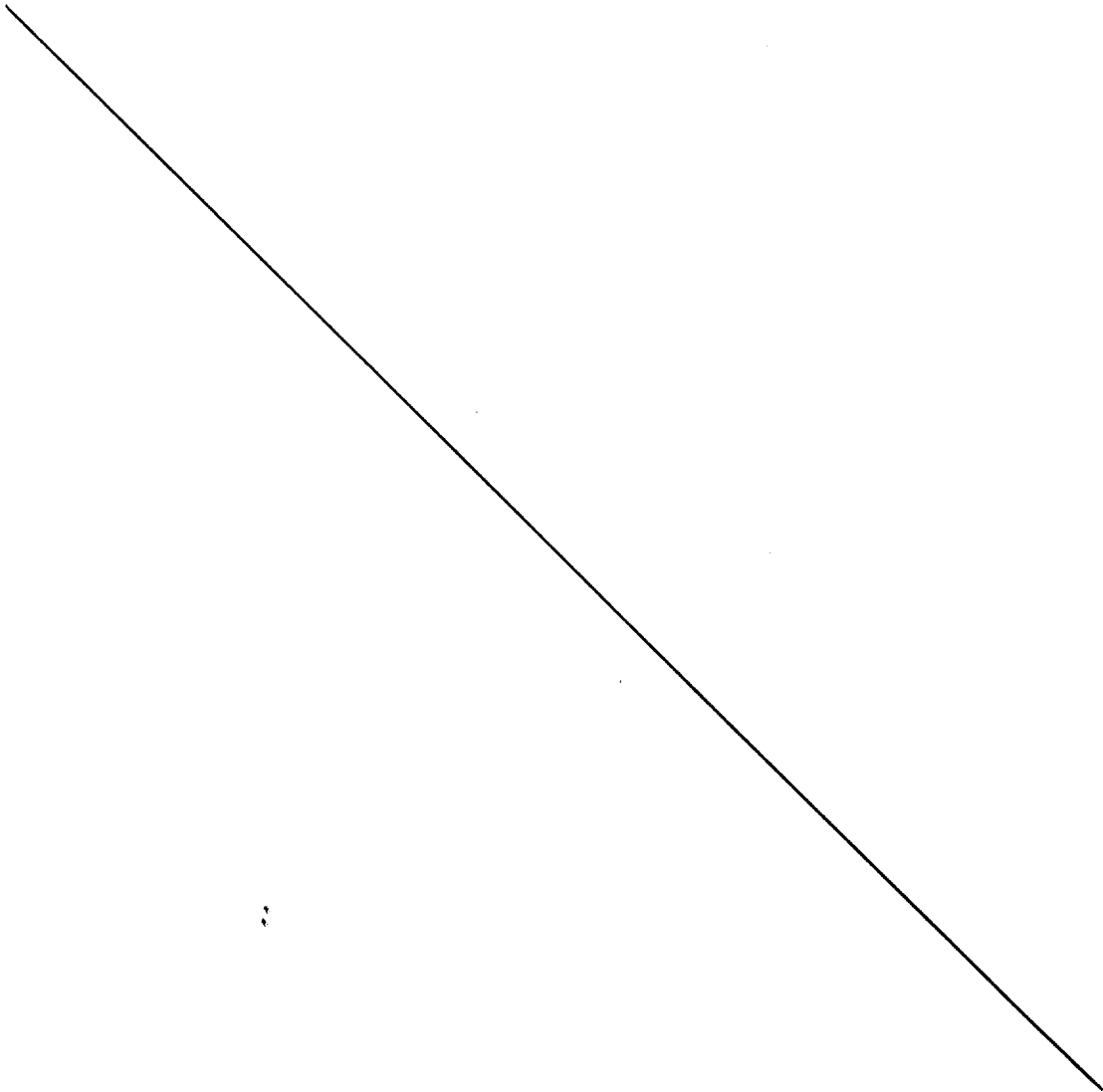
**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.61 is amended by adding paragraph (i) to read as follows:

**§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.**

\* \* \* \* \*

(i) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409(h) of the act, excluding the duties set out in section 409(h)(5) of the act, regarding premarket notification of food-contact substances:

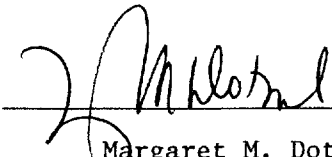


- (1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).
- (2) The Director, Office of Regulations and Policy, CFSAN.
- (3) The Director, Office of Premarket Approval, CFSAN.

Dated: 6-11-99

June 11, 1999

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

  
 Margaret M. Dotzel  
 Acting Associate Commissioner for  
 Policy Coordination



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